

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Priority***

This application claims priority from provisional application 60/524278, filed 11/21/03.

***Election/Restrictions***

Applicant elected Invention 1 and species 1 shown in figure 4A without traverse, on 10/27/10.

***Status of Claims***

Claims 1-3, 5, 9, 10, 13, 19, 20, 28, 29, 33, 34, 36-40, 43, 44, and 71-84 are pending.

Claims 4, 6-8, 11, 12, 14-18, 21-27, 30-32, 35, 41, 42, and 45-70 have been cancelled.

Claims 38 and 71-83 have been withdrawn from consideration.

***Information Disclosure Statement***

The IDS filed on 9/1/11 has been considered by the examiner.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

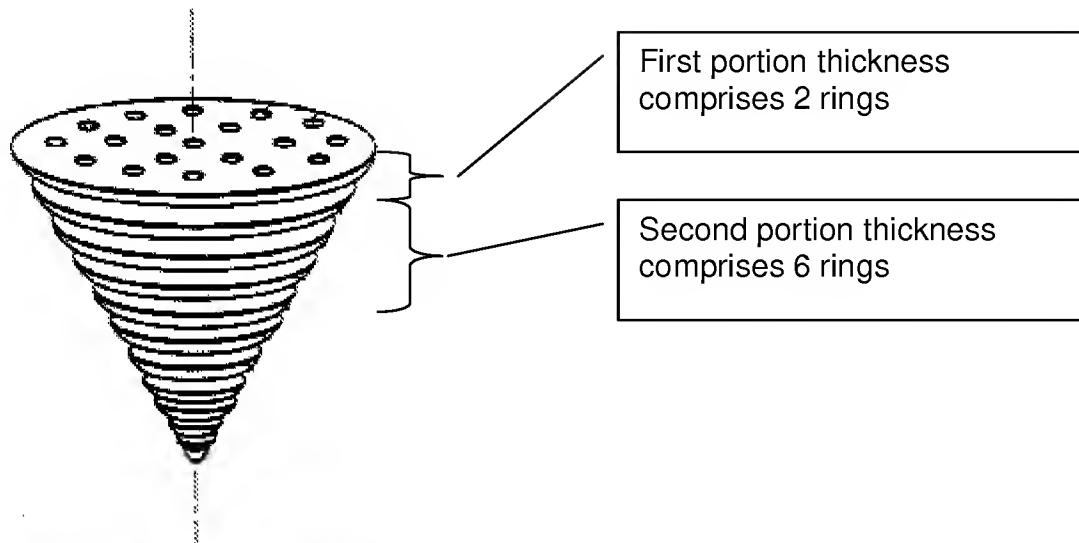
Claims 1-3, 5, 8, and 19 are rejected under 35 U.S.C. 103 as being unpatentable over Stone et al. (Stone) USPN 5,306,311.

Stone discloses the same invention being a cone shaped porous bioabsorbable plug implant comprising first and second circular planar portions having a tapered surface and a bioactive agent shown best in figure 4B

However, Stone does not specifically disclose the use of his implant in a cranioplasty or define specific ratios on two different portions of his implant. .

The amended claim language calling the applicant's invention a cranioplasty and referring to the applicant's desired location for its implant are considered language of intended use. Because the claims are directed at an apparatus and not a method of its use, the language is given limited weight. Depending on the specific circumstances of the implant site within the cranial bone, the device of Stone is fully capable of being used as a cranioplasty implant. Therefore the device of Stone reads upon the intended use language of the claim.

Additionally Stones implant discloses numerous portions which can be interpreted to have applicant's specified ratios of 1:1-3:1 or 2.75:1-3:1. See figure below for a marked up explanation:



***FIG. 4B***

Claims 9, 10, 13, 20, 28, 29, 31, 33, 34, 36, 37, 39, 40, 43, and 44 are rejected under 35 U.S.C. 103 as being unpatentable over Stone in view of Masters USPN 2002/0028243 A1.

Stone discloses the invention substantially as claimed being described supra. However, Stone does not disclose the TCP-PLC materials.

Masters teaches the use of medical implants comprising layers of TCP and PLC and that the layers are seeded with stem cells in the same field of endeavor for the purpose of providing a bioabsorbable implant capable of controlled drug delivery.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the materials of Masters with the implant of Stone in order to provide an implant capable of being readily absorbed into the implant site and deliver a controlled drug.

In regards to claims 10, 33, 34, 39, and 40 the claim language is requiring steps of making and using the implant. These steps are all given limited weight because the elected invention is the device and the device of Stone as modified by Masters is fully capable of being made and used in the claimed manner.

Additionally since the combination discloses the same material as required by the claims, it is considered to have all the same properties and perform in the same manner as that of the current application.

### ***Response to Arguments***

Applicant's arguments filed 9/1/10 have been fully considered but they are not persuasive. The applicant argues that Stone fails to disclose a first portion with a first thickness and a second portion with a second thickness, wherein the ratio of the first thickness to the second thickness is 1:1-3:1 or 2.75:1-3:1. This is not persuasive because the word choice of the applicant is extremely broad. In its current form the claim requires an implant having 2 **portions** having such ratios. Due to its tapered / layered form there are numerous lower portions with thicknesses that establish the claimed ratio with an upper portion.

The applicant further discusses the intended use of the implant within a cranioplasty, which failed to overcome the art of record. The device of stone is fully capable of being used in the same manner as that of the applicant's. Language of intended use is given limited weight and read upon by prior art if it is capable of performing the claimed tasks.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER D. PRONE whose telephone number is (571)272-6085. The examiner can normally be reached on Monday through Fri 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Sweet can be reached on (571) 272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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